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EXAMINER

ALEXANDER, LYLE

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1743

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/033,315
Filing Date: December 27, 2001
Appellant(s): STRAND ET AL.

Mr. Peter D. McDermott
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 5/19/05 appealing from the Office action mailed 8/16/04.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

No amendment after final has been filed.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

The following is a listing of the evidence (e.g., patents, publications, Official Notice, and admitted prior art) relied upon in the rejection of claims under appeal.

WO 99/60397	Holl et al.	11-1999
5,928,880	Wilding et al.	06-1999

6,475,364	Dubrow et al.	11-2002
6,494,433	Mastrangelo et al.	12-2002

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-6,8-19 and 27-35 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by WO 99/60397.

WO 99/60397 teaches a microfluidic device having a flow channel(20) and a plurality of capture regions. The abstract teaches an operative unit for analysis using optical, electrical, pressure sensitive or flow sensitive detection. Page 11 figures 6-7

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are described as having 7 sheets, which have been read on the claimed multilayer substrate. Pumps(P11-P15) control the sample flow through the device. Page 18 lines 4+ teach the materials of construction can withstand pressures of up to 600,000 psi, which have been read on the claimed excess of 100psi and 1000 psi. Page 18 lines 18+ and page 4 lines 18 through page 5 teach welding of the layers and a method of assembling the layers that has been read on claims 31-35. Page 14 teaches analysis region(304) that facilitates light absorption and photo detection of the analytes.

Claims 1-6,8-12 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Dubrow et al.

Dubrow et al. teach a microfluidic device for the characterization of a polypeptide. Columns 15-16 teach operative components that include electrodes to create an electric field to drive the fluid, electrochemical detectors, PMT's and a processor for overall control of the system.

Claims 1-6 and 8-14 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Wilding et al.

Wilding et al. teach a mesoscale sample preparation device incorporated into binding assays, polynucleotide determination/amplification and other analytical systems. Column 11 line 66 through column 12 teach describe figure 6B as teaches an analytical system comprising an analytical device(110) stacked upon a sample preparation device(10) in an appliance(70). A sample is supplied to inlet(74) where a pump(75) moves the sample to device(10) to device(110) through an interconnecting channel. Further heating and cooling elements(95) are taught. Column 13 lines 16+ teach

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attachment to the appliance by convention means and the "appropriate dimensioning of the devices" which has been read on the claimed alignment.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claims 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/60397, Wilding et al., or Dubrow et al. in view of Mastrangelo et al.

See WO 99/60397, Wilding et al. and Dubrow et al. supra.

These references are silent to the claimed thermal actuator. Mastrangelo et al. teach in column 1 lines 26+ thermal actuators are known in the art as a means to convert electrical energy to mechanical energy and are well adapted to serve as pumps because of their large mechanical advantage.

It would have been within the skill of the art to modify WO 99/60397 or Dubrow et al. in view of Mastrangelo et al. and use a thermal actuator to gain the above advantages.

Claims 20-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 99/60397, Wilding et al. or Dubrow et al.

See WO 99/60397, Wilding et al. and Dubrow et al. supra.

These references are silent to the claimed PEEK polymer.

The court decided In re Leshin (125 USPQ 416) the selection of a known plastic on the basis of its suitability of intended use is entirely obvious. PEEK is known to be inert, inexpensive and easy to work. It would have been within the skill of the art to modify WO 99/60397, Wilding et al. or Dubrow et al. and use a PEEK polymer to gain the above advantages as selection of a plastic based on its suitability of intended use.

Claims 15-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al.

See Wilding et al. supra.

Wilding et al. are silent to the claimed pressures.

The court decided In re Boesch (205 USPQ 215) that optimization of a result effective variable is ordinarily within the skill of the art. A result effective variable is one that has well known and predictable effects. The pressure chosen in a system is a result effective variable having the expected effect of increasing the reaction rate or speed of the reactions

It would have been within the skill of the art to modify Wilding et al. and use a pressure in excess of 100 psi as optimization of a result effective variable to achieve the well known and expected results of varying the speed and/or rate of the reaction.

Claims 27-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al.

See Wilding et al. *supra*.

Wilding et al. teach attachment of the layers, but are silent to the claimed welding.

It is notoriously well known in the art, as evidenced by the citations of Bentley et al. and WO 00/20157 in the 12/15/03 PTOL-1449, that welding of polymer layers is well known in the art. Welding is advantageous because the heat energy can be focused very precisely on the area to be attached and does not require additional adhesives that may possibly interfere with the reactants. It would have been within the skill of the art to further modify Wilding et al. and use well known welding techniques to attach the layers to gain the above advantages. Furthermore, the method of assembly steps, as in

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claims 31-35, would logically following the taught welding that is used for assembly of the device.

(10) Response to Argument

I. Appellants' state claims 1-6,8-19 and 27-35 are patentable over WO 99/60397

Appellants' state claims 1-6,8-19 and 27-35 are patentable over WO 99/60397 ('397 hereafter). Appellants' state '397 fails to teach "... atleast operative component on board a multi-layer laminated structure". Appellants' characterize '397 as teaching mechanisms that engage the surface rather than being mounted to the cartridge. Reading the claimed language "mounted aboard" in light of the specification, the Office concludes this language requires the means to be in contact with the cartridge. There is no teaching specifying the type of contact that is required. The Office maintains '397 teaches engagement (e.g. contact) of valves and pumps with the surface which has been properly read on the claimed "mounted aboard".

Appellants' state claim 13 defines over '397 because a microscale device having microchannels is not taught. '397 teaches on page 3 lines 7+ "microscale channels" and on page 14 lines 25+ samples of "15 microliters". In the absence of Appellants' better defining what is intended by "microfluidic", the Office maintains '397 teaches a device with microchannels using samples of 15 microliters is indistinguishable from the pending claims.

Appellants' state '397 fails to teach a multilayer device that is "selectively welded" together. '397 teaches on page 4 lines 18 through page 5 and page 18 lines 18+

welding the layers together. With respect to the term "selectively", the Office maintains '397 meets this limitations because only welding of the edges is taught.

Appellants' state '397 is not anticipatory of claims 31-35 directed to a method of assembling the layers. The Office maintains, the teachings of '397 are sufficient to teach the assembly and welding of the multiple layers.

II. Appellants" state claims 1-6 and 8-12 are patentable over Dubrow et al.

Appellants' state Dubrow et al. does not teach a microfluidic device and at least one operative component mounted aboard the device. Dubrow et al. teach in paragraph 15 lines 37+ a microfluidic device(100) comprising a channel network. This has been read on the claimed microfluidic device. Further, paragraph 15 lines 37+ teaches many devices that are "mounted aboard the device" such as electrical controller(202), electrodes(204-234), etc.

III. Appellants" state claims 1-6,8-19 and 27-35 are patentable over Wilding et al.

Appellants' state Wilding et al. fail to teach a microscale multilayer device with "operative components mounted aboard". Wilding et al. teach in column 3 lines 25+ the device is "... a microfabricated sample preparation device ... provides microvolume fractions of test samples ...". Further, column 7 lines 27+ teach dimensions and volumes of the device that are consistent with the claimed "microscale device". Figure 1 teaches a substrate(11) with a cover(29) which has been read on the claimed "multilayer" limitations. Also figure 6b shows a multilayer configuration. Finally, column 12 teaches pumps(75), pressure sensor(96), heating/cooling element(95) and analytical device(122) have been read on the claimed "operative components".

Appellants' state Wilding et al. fails to teach a light sensor. Column 14 lines 48+ teach detection of a chromophore which has been read on the "light sensor".

Appellants' state Wilding et al. fails to teach at least one electronic memory. Wilding et al. teach in column 12 lines 62+ a microprocessor that has been read on this limitation.

Appellants' state Wilding et al. fail to teach the claimed pressure range of 100-1000 psi. The Office agrees Wilding et al. does not teach the claimed pressure range. However, under 35 USC 103 the pressure selected would have been a result effective variable and within the skill of the art. Appellants' have not fully traversed the 35 USC 103 rejection by pointing out why the motivation is improper. The Office maintains the rejection of record.

Appellants' state Wilding et al. fail to teach a multilayer device that is "selectively welded" together and a method of assembling the layers. The Office agrees Wilding et al. does not teach these limitations. However, the Office maintains these limitations would have been obvious under 35 USC 103 as stated on the record. Appellants' have not fully traversed the 35 USC 103 rejection by pointing out why the motivation is improper. The Office maintains the rejection of record.

IV. Appellants' state claim 7 is patentable over Wilding et al. (USP 5,928,880), '397 or Dubrow et al. in view of Mastrangelo et al.

Appellants' state Mastrangelo et al. fail to cure the deficiencies of Wilding et al., '397 or Dubrow et al. In the absence of Appellants' arguing the motivation put forth on record is improper, the Office maintains these rejections should be maintained.

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V. Appellants' state claims 20-26 are patentable over '396, Wilding et al., Dubrow et al.

Appellants' traverse the motivation used by the Office stating, "there is no such rule". In the absence of citing a court decision stating otherwise, the Office maintains In re Leshin is proper. The Office maintains this rejection.

VI. Appellants' state claims 15-19 are patentable over Wilding et al.

Appellants' state Wilding et al. fail to teach the claimed pressure range of 100-1000 psi. The Office agrees Wilding et al. does not teach the claimed pressure range. However, under 35 USC 103 the pressure selected would have been a result effective variable and within the skill of the art. Appellants' have not fully traversed the 35 USC 103 rejection by pointing out why the motivation is improper. The Office maintains the rejection of record. The remaining issues have been addressed supra.

VII. Appellants' state claims 27-35 are patentable over Wilding et al.

All of these issues have been addressed supra.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

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For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Lyle A. Alexander

A handwritten signature in cursive script that reads "Lyle A. Alexander".

**LYLE A. ALEXANDER
PRIMARY EXAMINER**

Conferees:

Ms. Jill Warden

Mr. Patrick Ryan